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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,828	12/09/2003	Ian D. Faulkner	PZ9918 CON	4379

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Amerhsam Health, Inc.
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EXAMINER	
GILBERT, SAMUEL G	
ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,828	FAULKNER ET AL.	
	Examiner	Art Unit	
	Samuel G. Gilbert	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-10,12,13,15,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-10,12,13,15,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5, 7-10, 12, 13, 15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langton et al(5,460,592) in view of Bolea(5,863,790).

Langton teaches a method of making and sterilizing a seed train. The applicant's attention is invited to column 2 lines 60-64, showing the method of heating and subsequently cooling to make the seed train semi-rigid. Column 3 lines 10-13 that teaches the device can be stiffened and sterilized at the same time. Column 6 lines 1-3 show a temperature range of 150-185 C for 1 hour to stiffen the material. The examiner is taking element -13- as a closed container. Sleeve –28- is gas impermeable. I-125 is set forth in column 5, lines 14-21. It is inherent that the seeds a free of moisture. Regarding claim 12 – the heat is dry heat. The applicant's attention is invited to column 6, line 1. However Langton et al does not teach a time of at least two hours for sterilization. It is old and well known in the medical art that when using dry heat for sterilization the typical time period is at least two hours as shown by Bolea column 1 lines 39-42. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use a time period of at least two hours for dry heat

sterilization for the device of Langton et al as set forth in Bolea to ensure the device is properly sterilized.

Claims 9 and 19 - the seeds may be I-125 and Pd-103, column 5 lines 5-21.

Claim 10 – It is the examiner's position that the seeds of Langton et al are inherently free of moisture but if they would include at the beginning of the dry heat sterilization process the seed would be free of moisture at the end of the dry heat sterilization process.

Claim 14 – the applicant's attention is invited to the embodiment of figure 23.

Claim 18 - it is the examiner's position that the elements are isotropic, unless specifically designed to provide a dose distribution, which is not isotopic, the radiation distribution of most seeds known in the medical arts are isotropic. The applicant has provided no evidence that the seeds of Langton et al are out of the ordinary and therefore are considered to be isotropic.

Claims 7 and 15 - the devices after sterilization are shipped the end user. The end user would need to know what specific radiation train is contained in the sterile package to decide which seed train to use. Labels are well known in the medical arts to provide end users with the information they need. The examiner is taking official notice that end user package labels are well known in the medical arts and would have been obvious to use with the container of Langton et al. to provide the end user with the required information.

Claim 8 - when using an autoclave it is known to sterilize more than one instrument at the same time. It would have been obvious to one of ordinary skill in the

art at the time the invention was made to sterilize more than one device at a time as a duplication of elements which is within the skill of one of ordinary skill in the art.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kan 6,106,455 in view of the combination of Langton et al (5,460,592) and Bolea(5,863,790) as applied to claim 1 above. Kan teaches sterilizing loose seeds with steam. Langton and Bolea teach using dry heat in the range claimed for the time claimed by the applicant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use dry heat sterilization with the device of Kan as a substitution of functionally equivalent elements as taught by Langton et al and Bolea.

Response to Arguments

On page 3 of 7 in the applicant's remarks the applicant argues that "one skilled in the art would be discouraged from increasing the one-hour time for sterilization in Langton because the seed train is stiffened and sterilized in one hour." The examiner disagrees and as previously pointed out that the one hour time limitation set forth in column 1 lines 1 and 2 is only to "stiffen the bioabsorbable material" to maintain the strand rigid and maintain its shape. Langton et al does not indicate that one-hour of dry heat will stiffen and sterilize the seed strand only that the one hour time limit will "stiffen" the seed strand.

It is the examiners position that if the seed strand of Langton et al were to be stiffened and sterilized separately the process would be as follows as set forth by Lagnton, column 2 line 56 through column 3 line 9.

The seed strand would first be heated for one hour to stiffen the seed strand, column 6, lines 1 and 2. The seed strand would then be cooled as set forth in column 2 lines 62-65. After the strand is cooled the strand would be packaged and then sterilized by gas or gamma irradiation. This method would require the strand to be handled and moved between the stiffening and packaging steps and then handled and moved again between the packaging and sterilizing steps.

Langton does not set forth dry heat sterilization in a procedure where the strand is stiffened and sterilized separately. However, because dry heat sterilization is old and well known in the medical arts one of ordinary skill in the arts would have found it obvious to use dry heat sterilization in place of gas or gamma sterilization. In this procedure, the strand would be stiffened by dry heat for one hour, cooled, handled and transported to be dry heat sterilized for at least two hours which is what is old and well known as the standard in the art as shown by Bolea then the strand would be cooled and packaged, for a total time in dry heat of at least 3 hours.

Langton does set forth that the process of stiffening and sterilizing may be completed together to produce a "one step" manufacturing process. In this method, the strand would be placed in dry heat for at least two hours as shown by the combination of Langton et al and Bolea, the strand would be stiffened after the first hour of the

heating while sterilization would not be finished until the strand has been in the dry heat for at least two hours. The strand then be cooled and packaged.

Combining the steps of stiffening and sterilizing requires a total heating time of at least two hours while the method using separate stiffening and sterilizing with dry heat requires a total heating time of at least three hours.

Therefore, the combination of the teachings of Langton et al and Bolea would have been obvious and the references do not teach away from an at least two hour time period as argued by the applicant.

The applicant argues that the temperature set forth in claim one is not anticipated by the combination of Langten et al and Bolea. The examiner does not understand why the applicant does not feel that a temperature range of 180°C and above anticipates the claimed temperature range of at least 140°C. The applicant's attention is again directed to the examiners response to arguments of the office action of 8/17/2006.

The applicant also argues that Bolea does not teach dry heat sterilizing radioactive seeds and that the framework of 35 U.S.C. 103 may not be used to pick and choose only so much of a reference as will give support for a given position taken by the examiner to the exclusion of other parts of the reference necessary to the full appreciation of what such a reference fairly suggests to one skilled in the art.

In response it is the examiner's position that the applicant is correct that Bolea does not teach dry heat sterilization of radioactive seeds. Bolea does however teach that the generally accepted time period for dry heat sterilization is two hours. The examiner has not used Bolea to show dry heat sterilization of radioactive seeds only the generally accepted time period for such sterilization. The examiner has reviewed Bolea in its entirety and believes that the dry heat sterilization time period of at least two hours is clearly taught in Bolea and nothing in Bolea teaches away from using such a time period in dry heat sterilization of radioactive seeds.

Langton et al does teach dry heat sterilization of seeds but does not set forth the time period required for such sterilization as set forth above.

The applicant further argues that Langton et al teaches that the seed strand is sterilized and stiffened in one hour and therefore teaches away from at least two hours as set forth by the examiner.

The examiner disagrees because the applicant has failed to show that Langton et al sterilizes and stiffens the seed strand in only one hour. The examiner has pointed out above the one hour time period set forth by Langton et al is only for stiffening the seed strand and is generally considered not sufficient for sterilization as set forth by Bolea.

Lastly the applicant argues that the seeds of Langton et al are out of the ordinary and thus are isotropic. Further, the dose distribution is out of the ordinary, last three lines of page 5 of the applicant's arguments. The examiner has reviewed Langton et al

including the lines cited by the applicant and has not found the seeds are out of the ordinary, the seeds are isotropic or the dose distribution is out of the ordinary. Further, even if such was found in Langton et al the examiner believes the arguments are not persuasive because limitations to the argued subject matter does not appear in or are precluded by the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Samuel G. Gilbert
Primary Examiner
Art Unit 3735

sgg